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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/312,351 05/14/99 WOLFF

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EXAMINER

SCHNIZER, R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED:

05/23/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/312,351

Applicant(s)  
Wolff

Examiner  
Richard Schnitzler

Group Art Unit  
1632



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-18 are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6, 15, and 16, drawn to a composition comprising a biologically active polynucleotide, a disulfide containing compound, and to a method of using the composition, classified in class 514, subclass 44.
- II. Claims 1-3, 5, 6, 15, 17, drawn to a composition comprising a biologically active polypeptide, a disulfide-containing compound, and a method of using the composition, classified in class 514, subclass 2.
- III. Claims 7-14 and 18, drawn to a disulfide-containing compound and a method of use, classified in class 424, subclass 707.

Claims 1-3, 6, and 15 are generic to a plurality of disclosed patentably distinct species. If a group containing any of these claims is elected, the generic claim or claims will be examined to the extent that it is defined by the classification of the elected group.

The inventions are distinct, each from the other because of the following reasons:

The composition of group I comprises a polynucleotide, and the composition of group I comprises a polypeptide. The inventions are related because the polynucleotide could encode the polypeptide, and could be used to produce the polypeptide. The inventions are distinct because

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the polynucleotide could encode antisense RNA or a ribozyme, and because the polypeptide can produced by other means, such as purification from the natural source.

The compositions of groups I and II are related to the disulfide compound of group III, because the compositions of groups I and II comprise the compound of group III. The inventions are distinct because the addition of a biologically active molecule to the disulfide compound alters the structure and functionality of the composition. The altered compositions may be used for delivery of a polypeptide or a polynucleotide to a cell, whereas the unaltered composition cannot. The disulfide compound may also be used for purposes other than delivery, such as cross-linking compounds to a solid support.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

***Election of Species***

Claims 1-18 are generic to a plurality of disclosed patentably distinct species comprising disulfide-containing compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed disulfide-containing compound, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached at 703-308-2035. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Richard Schnizer, Ph. D.



BRUCE R. CAMPELL  
PRIMARY EXAMINER  
GROUP 1800